KENNY C. GUINN
Governor

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

PHARMACY & THERAPEUTICS COMMITTEE

Location of Meeting
Las Vegas Chamber of Commerce
3720 Howard Hughes Pkwy
Las Vegas, NV 89109

Meeting Minutes- Draft
April 28, 2005
Time: 1:00 p.m.

Committee Members Las Vegas:
Steven Phillips, MD, Chairman
Judy Britt, Pharm.D.
Diana Bond, R.Ph.
Linda Flynn, R.Ph.
Larry Pinson, Pharm.D.
Tom Wiser, Pharm.D. (called-in)

Absent:
Alan Greenberg, MD, Carl Heard, MD, Robert Horne, MD, Susan Pintar, MD

Others Present:
Darrell Faircloth AGO, Carla Sloan Advisory Committee, Joseph Tyler Advisory Committee, Coleen Lawrence DHCFP, Vickie Langdon DHCFP, Jeff Monaghan FHSC, Shirley Hunting FHSC, Dawn Daly FHSC, Katie Johnson FHSC, Bert Jones GSK, Bret Paiker NHO, Tom Wood Wyeth, Roland Baldwin Wyeth, Johnna Nelson Lilly, Laurie Squartsoff Eli Lilly, Ann Speiser OMP, Richard Smith Pfizer, Steve Schaerper AZ, K. Yozie Cephalon, Michael Karagiozig Cephalon, Oscar Johnson 3M, Sedrick Spencer Roche, Megan Bender NHS, David Abrahamson Merck, Kathy Phillips Merck, John Schaeffer, MD, Karen Theesen GSK, Beth Ann Pope Pfizer, Scott Goldfarb Pfizer, Kara Smith Boehringer Ingelheim, Bruce Martz Boehringer Ingelheim, Claudia Dodge Pfizer

I. **Call to Order and Roll Call**
Chairman Steven Phillips called the meeting to order at 1:03 p.m.

II. **Review and Approval of October 28th, 2004, Meeting Minutes**

Motion: Larry Pinson motioned to accept the minutes as written.
Second: Linda Flynn
Ayes: Unanimous
Motion Carried

III. **Report on Preferred Drug List Status - First Health Services – Approval Rate for PDL Exception Requests and Clinical Edits**

Dr. Monaghan presented a three month overview of Call Center activity. He stated that the average requests per day related to the PDL was 37. Approximately 50% of the requests were approved, and in 50%, therapy was changed. He stated that Nevada experiences a higher rate in change of therapy as compared to other states.

Dr. Monaghan also presented an overview of market shift examples. Significant market shift to preferred agents occurred in the Beta-Blockers, Bone Ossification Suppression Agents, PPI's, Ace Inhibitors and Non-Barbiturates, Sedative-Hypnotics, and Quinolones.

Dr. Phillips asked if claims in 2000 are equal to claims in 2004; e.g., the number of Actonel claims in 2000 was 934 and 1,269 claims in 2004. Is this due to increased usage?

Dr. Monaghan responded that the eligible recipients have increased and utilization in this class of drugs has also increased.

Dr. Phillips requested that future reports include a weighting factor.

IV. **Report on Drug Use Review Board Activities – First Health Services**

Quantity Limitation Edits

Dr. Monaghan reported that the DUR Board has implemented quantity limit recommendations (see attached). The intent of the edits is to prevent over-billing, most of which is inadvertent due to pharmacy entry of incorrect billing units.

Denials for ProDUR Severity Level One Messages

The DUR Board recommended the requirement of a response on all severity level one ProDUR messages. The pharmacist will be required to enter the intervention and the outcome. Implementation is scheduled for June 15, 2005.

Dr. Phillips referred to the DUR Board minutes and stated that he liked the fact that the emphasis is truly on patient safety.

Dr. Pinson asked who determines the severity levels and Dr. Monaghan stated that they are from First Data Bank.

Continuity of Care Considerations – Antidepressant Medication

At the October meeting, the P&T Committee requested that the DUR Board consider revising PDL exception criteria to allow patients discharged from acute mental health facilities on a non-preferred antidepressant to remain on the drug. Dr. Monaghan read the motion from the DUR Board meeting:

> MOTION: Dr. Parker made a motion for those patients discharged from acute mental health facilities on a non-preferred antidepressant be allowed to continue on the antidepressant they received and responded to in the hospital for up to 90 days following discharge. After the 90 days, the patient must meet one of the five PDL Exception Criteria.
> SECOND: Keith Macdonald
> VOTES: Unanimous

MOTION CARRIED

A sixth criterion will be added to the PDL exceptions which will reflect this motion.

Non-Steroidal Anti-Inflammatory Drug Products (NSAIDS), Including Those Known as COX-2 Selective Agents

Dr. Monaghan referred to the FDA's "Analysis and Recommendations for Agency Action Regarding Non-Steroidal Anti-Inflammatory Drugs and Cardiovascular Risk". The DUR Board has asked that in addition to the existing criteria for COX-2's, that a statement be added to the prior authorization form to include the FDA's warning of potential cardiac complications associated with this class of drug. The statement would be for awareness purposes and not a barrier to getting the medication if the patient meets the criteria. In addition, the DUR Board requested a review of black box warnings for all drugs that have prior authorization requirements.

Dr. Phillips stated that he is comfortable with the DUR Board's review and approach with COX-2's and the PA process and feels the P&T Committee does not need to review this class of drugs at this time.

V. **Serotonin Agonists ("Triptans")**

Public Comment

Karen Theesen, Glaxo Smith-Kline, spoke in support of Imitrex® to the PDL.

Dr. Pinson asked regarding use in pediatrics and adolescents.

Ms. Theesen stated that Imitrex® injectable and tablets are not FDA approved for use in pediatrics and adolescents. The Academy of Pediatrics indicates ibuprofen or Imitrex® nasal.

Dr. Pinson asked if her company is trying to get that indication.

Ms. Theesen replied not at this time.

David Abrahamson, Merck, spoke in support of Maxalt®. In response to Dr. Pinson's question regarding adolescents, he stated that his company has conducted studies in adolescents between the ages of 10-16 using the 5mg dose and saw trends toward efficacy, but not the type of efficacy as compared to adults. As a result, bringing a drug to market which isn't absolutely consistent on efficacy isn't the right thing to do.

Ann Speiser, Ortho McNeil, spoke in support of Axert®.

Dr. Britt asked if Ortho McNeil will be coming out with other dosage forms in the future.

Ms. Speiser replied that they have a melt form in formulation and in study but there is no timeline at this point.

Dr. Ansarinia, headache specialist, stated that the issue in clinical practice is the triptans on formulary are quick acting but have a short half-life and the headache recurrence rate is high. He spoke in support of longer-acting triptans to improve efficacy and hopefully reduce the recurrence rate.

Beth Ann Pope, Pfizer, spoke in support of Relpax®.

Dr. Britt asked if there were superiority outcomes using 20mg Relpax®.

Ms. Pope replied that 40mg is the recommended adult dose. 20mg is available for use in special populations if the physician has determined there are tolerability issues or some sensitivity to triptans.

John Schaeffer, DO, neurologist in private practice, stated that because of the different types of migraines people get and the different approaches to treatment, he supported the inclusion of all formations of triptans be included. In terms of pediatrics and adolescents, the problem with the standard measurement in migraine studies is what happens two hours after the drug or placebo is taken. Pediatric/adolescent migraines tend to be shorter than adult migraines and as a result, even the placebo group had a large number of people who were better at two hours. If they had a one hour measurement or just included kids who had headaches that lasted four hours or longer, the results were different. Based on the way they currently do the studies, he doubted these products will be approved within that group.

Drug Class Review – First Health
Dawn Daly, FHSC, informed the Committee that included in their packets is written public testimony for their review. She presented an overview and comparison of the drugs within the class (attached) and recommended they be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Each Class and Identify Exclusions/Exceptions for Certain Patient Groups
Dr. Pinson moved that all drugs within this class be considered therapeutic alternatives and that a nasal spray and injectable be included on the PDL and added that drug-to-drug, they are therapeutic alternatives. Dr. Britt felt that due to patient variability in response to these medications, the choices should not be limited to one or two and agreed that, overall, they are therapeutically equivalent.

Ms. Bond asked that if there is treatment failure, is there still the ability to obtain prior authorization for another agent? Would past history experience be accepted for immediate PA; i.e., if eletriptan was the preferred agent but the patient has a past history of failure with this drug, would a PA be authorized for a non-preferred agent.

Dr. Phillips stated that PDL exception criteria requires failure of two preferred medications within the same class, however, if there is only one preferred medication, the PA would be authorized.

Dr. Monaghan suggested that the Committee consider grandfathering for a 90-day period.

Dr. Wiser agreed and stated that if the patient is on an agent and it's been successful for the past 90 days, they could be grandfathered.

Motion: Tom Wiser moved to accept these agents as therapeutic alternatives with consideration given to dosage forms.
Second: Diana Bond
Ayes: Unanimous
Motion Carried

Motion: Tom Wiser moved that if a patient has been successfully treated on an agent within the previous 90 days, that agent be grandfathered.
Second: Diana Bond
Ayes: Unanimous
Motion Carried

At the request of Dr. Monaghan, Dr. Phillips called for a 5 minute recess at 2:00 p.m. The meeting was reconvened at 2:06 p.m.

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Jeff Monaghan stated that it is the recommendation of DHCFP and FHSC to add all dosage forms of zolmitriptan (Zomig®), which includes a nasal spray, all dosage forms of rizatriptan (Maxalt®), which includes a rapidly dissolving oral tablet and sumatriptan (Imitrex®) injectable to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Motion: Diana Bond moved to accept all dosage forms of zolmitriptan (Zomig®), all dosage forms of rizatriptan (Maxalt®), and sumatriptan (Imitrex®) injectable to the Preferred Drug List.
Second: Judy Britt
Ayes: Unanimous
Motion Carried

VI. **Review of Stimulants/ADHD Drug Class with Specific Emphasis on Narcolepsy and Sleep Disorders**

Public Comment

Michael Karagiozig, Cephalon, spoke in support of Provigil®.

Dr. Wiser asked if Mr. Karagiozig had any comments regarding the use of the other agents within this class.

He stated that his background is fours years with the State in mental health and five years with the Department of Prisons. His experience with the other amphetamines has been an incredible diversion problem. Las Vegas is one of the highest areas for

amphetamine abuse with only four other cities ranking higher and is also one of the highest inlets for those drugs most of that coming from California. They also have a higher side-effect profile. The particular populations that are appropriate for Provigil® are at a higher cardiovascular risk. Using traditional amphetamine stimulants increases the risk for cardiovascular events. Provigil® appears to be safer.

Johnna Nelson, Eli Lilly, asked for clarification, that if Strattera is being reconsidered, she will provide information, or is the emphasis on narcolepsy and sleep disorder.

Dr. Phillips stated that the emphasis is on narcolepsy and sleep disorder.

Drug Class Review – First Health Services

Jeff Monaghan reviewed the history of this issue. This class of drugs was originally reviewed at the June, 2004, meeting. At that meeting, Dr. Horne motioned that all the drugs in this class be considered therapeutic alternatives. The vote was unanimous. At the August 12th meeting, during which the PDL selection process occurred, there was extensive discussion about this class. Dr. Heard felt strongly that Provigil® should remain non-preferred so it would not have unlimited use. Dr. Horne argued toward deletion from the PDL entirely which would allow open access to the drug. After further discussion, Dr. Horne accepted a friendly amendment to designate Provigil® as non-preferred. That vote was unanimous. Dr. Horne asked that Provigil® be placed on the agenda for discussion at a future meeting. Provigil® was again discussed at the October 28th meeting. At that time, Dr. Horne requested that Provigil® not be on the preferred list but allow use without a prior authorization for FDA approved indications related to sleep disorders. Dr. Heard requested that rather than take action, that all medications used for narcolepsy and sleep disorders be reviewed at the next meeting.

Dr. Monaghan presented an overview and comparison of the drugs within the class (attached). He stated that in calendar year 2004, the number of physician paid claims for Medicaid patients with a diagnosis of narcolepsy was 38. From a narcolepsy/sleep disorder standpoint, he recommended the drugs in this class be considered therapeutic alternatives.

Ms. Bond asked if a report for sleep apnea as a coded diagnosis was reviewed and he replied no. She asked what is the current utilization of Provigil®.

Dr. Monaghan stated there are approximately 1,000 claims per year or approximately 100 patients per year. Of the 100 patients, 8-9 patients' claims include the diagnosis of narcolepsy. He added that PA's are being approved through the Call Center for non-narcolepsy indications.

Dr. Britt asked if the Call Center uses criteria that would not be FDA approved labeling but would be common usage. Are the criteria written?

Dr. Monaghan replied that if there is peer-reviewed literature available and the clinician makes a good case, some are approved. The criteria is presented by the requestor and verified by the Call Center.

Dr. Phillips: haven't we already clarified for a specific diagnosis?

Dr. Monaghan replied that the drug can be made available without PA for the specific diagnosis of sleep apnea or narcolepsy. Considering the low incidence of use, this would be reasonable.

Dr. Wiser asked if modafinil (Provigil®) will be going generic soon.

Dr. Monaghan stated that it's his understanding it will be generic soon but he did not know the date and that they (Cephalon) are working on other formulations to protect that patent expiration.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Each Class and Identify Exclusions/Exceptions for Certain Patient Groups

Motion: Diana Bond made a motion that since First Health has the ability to identify these patients based on the diagnosis code, that Provigil® be added to the Preferred Drug List with the designation that it is available for the diagnoses of sleep apnea and narcolepsy.
Dr. Britt made a friendly amendment to include diagnoses that would be approved and commonly used in the community. In some situations, it may be appropriate to use it in MS.
Ms. Bond stated that she didn't disagree and would be open to adding MS to the list but felt they should be more specific, otherwise there would be no guidance.
Dr. Britt asked if the ICD-9 would be on the prescription and Ms. Bond stated it would be available through First Health.
Dr. Britt asked Dr. Monaghan if criteria will be written and do we have to define the diagnostic criteria for the utilization or would this need to go to the DUR Board.
Dr. Monaghan stated and Dr. Phillips agreed that, technically, it would have to go to the DUR Board. By applying the specific ICD-9 code, the claim would process, bypassing the Call Center. Dr. Monaghan clarified with Dr. Britt that what she is suggesting is adding criteria for utilization. She stated that is correct. He said that would require a call to the Call Center for prior authorization. He also clarified with Ms. Bond that what she is suggesting is that if the ICD-9 code is applied, the claim will go through without a PA.
Ms. Bond stated that is correct for that group of patients realizing that there still is opportunity in these other populations to call and get a prior authorization. She added that by not segmenting this group off for its treatment diagnosis and lumping it with the amphetamines for ADHD, confusion has resulted. It doesn't belong there. It is a very distinct group. Living in Las Vegas and with the issues nationally concerning the consumption of amphetamines, the responsible thing to do is have the drug available for appropriate treatment and diagnoses, and it should be on the Preferred Drug List.
Dr. Wiser asked Dr. Monaghan if the PDL exception criteria is applied, can you cover those other bases that you mentioned earlier.
Dr. Monaghan replied that the exception criteria states for unique or specific FDA approved indications that are unique to the non-preferred drug. It would have to be made on a case-by-case basis to the Clinical Call Center.

Dr. Phillips agreed adding that he supported staying with narcolepsy and sleep disorder at this point with the appreciation that literature is developing. He asked Dr. Britt if she would like to withdraw the amendment.
Dr. Britt stated that she felt the amendment does not need to be removed but how the diagnosis is available to the pharmacist needs to be defined in order for that claim to go through.
Coleen Lawrence stated for clarification that the PDL Exception Criteria states it is peer-reviewed literature or an FDA-approved indication, and for the diagnosis, as with the other prior authorization services in place, the physician does write the ICD-9 code on the prescription.
Dr. Phillips called for a second to Ms. Bond's motion.
Second: Larry Pinson
Ayes: Unanimous
Motion Carried

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Jeff Monaghan stated that it is the recommendation of FHS and DHCFP to maintain the drugs currently on the PDL for the ADHD stimulant drug class and that Provigil® be preferred if the ICD-9 code is present for sleep apnea or narcolepsy. The PDL will be revised to reflect this change.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Motion: Diana Bond motioned that Provigil® be added to the Preferred Drug List for the diagnoses of narcolepsy and sleep apnea.
Second: Larry Pinson
Ayes: Unanimous
Motion Carried

VII. **Addition of Zofran® (ondansetron) to the Preferred Drug List (PDL)**

Public Comment
No Public Comment

Recommendation by First Health Services to Add Zofran® (ondansetron) to the Preferred Drug List
Jeff Monaghan stated that in the Antiemetic Category, First Health recommended and the Committee adopted Kytril® as the sole agent on the Preferred Drug List. Kytril® has no pediatric indications. He recommended the addition of all dosage forms of Zofran® but restrict it to patients less than 18 years old.

Committee Discussion and Approval of Zofran® for Inclusion in the PDL for Patients < 18 Years Old

Motion: Diana Bond made a motion to add ondansetron (Zofran®) to the Preferred Drug List for use in populations under the age of 18.
Second: Linda Flynn
Dr. Wiser asked if that includes the prevention of nausea.

Dr. Monaghan replied it is for the prevention of chemotherapy-induced nausea.
Ayes: Unanimous
Motion Carried

VIII. **Discussion of Annual Preferred Drug List Review Process**

Jeff Monaghan presented a proposed outline for annual review of the Preferred Drug List.

Dr. Monaghan stated that the Committee is required to review the PDL annually, and asked Darrell Faircloth, DAG, to research if the Committee is required to adopt the PDL again; i.e., what actions are required if there are no changes.

Diana Bond suggested the length of time for public comment be reduced and that public comment be limited to drug classes with changes.

Coleen Lawrence stated that of the 31 drug classes, 20 are being recommended for no changes at this time. The intent is to review new things that may have occurred during the year such as physician feedback, committee request for re-review, new drugs on the market, etc. She suggested that an action should be taken on the 20 classes which will remain as is and that public comment can be limited to less than five minutes. The chairman can direct that only new information can be brought forward at the time of this public comment.

Dr. Phillips recommended public comment for the annual drug review be limited to two minutes and notification of the time limit be posted prior to the meeting.

Darrell Faircloth will research the two minute limit for public comment to determine if it is an appropriate time length.

Coleen Lawrence suggested grouping the three classes that are coming up for bid enhancement, make one action and take public comment based upon that action. She also suggested limiting public comment to new information. Following the annual review, if new drugs or information are released within the classes included in the annual review, the committee can re-review the class at the next scheduled meeting or call a special session.

IX. **Review of Next Meeting Location, Date, and Time**

The next meeting is scheduled for July 28, 2005, at 1:00 p.m. in Carson City.

Diana Bond encouraged videoconferencing the meetings be reconsidered.

Coleen Lawrence announced that due to term limitations and one resignation, there will be three positions opening on the P&T Committee. As part of the nomination process, she will send letters next week to Pharma, Retail Association of Nevada, Nevada Association of Chain Drug Stores and the Board of Medical Examiners requesting nominations. If the committee has recommendations, she requested a letter with CV attached be sent directly to her by May 15, 2005. Recommendations will be sent to the Director who in turn will forward them to the Governor. The Governor will appoint a selection committee. New appointments will be effective July 1, 2005.

X. **Public Comment**

Bert Jones, Glaxo Smith Kline, requested that the criteria for testimony for the July meeting be on the FHSC website 30 days prior to the meeting.

Tom Wood, Pharma, recommended that First Health present their reviews and recommendations before public comment. This will allow the speakers to address the issues raised by First Health. Although the general overviews and comparisons are available on the website before the meeting, the recommendations might be useful for people to tailor their talks.

Dr. Monaghan responded that the review process will not change and clarified the process for the annual review. The drug classes to be reviewed and the drug reviews will be posted to the website 30 days prior to the meeting. The list of classes with no proposed changes will also be posted.

Johnna Nelson, Eli Lilly, asked the committee to consider a minimum of a three minute time limit as it is difficult to make any substantial claims about new information in two minutes or less. Three minutes is adequate time to provide new information.

XI. **Adjournment**

Motion: Linda Flynn motioned for adjournment.
Second: Judy Britt
Ayes: Unanimous
Motion Carried
Meeting adjourned at 2:59 p.m.